09/017,715

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/017,715	02/03/98	JI	H 1488.0810003

EXAMINER

HM12/0606

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ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 06/06/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/22/00.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10-12, 14-79 is/are pending in the application.

Of the above, claim(s) 10-12, 14-15, 79 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 16-78 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

1. Applicant request the rejoinder of claim 79 to examined claims 16-78. Applicant argues that a reasonable number of independent and distinct nucleotide sequences, usually up to ten, are permitted to be claimed in a single invention (see 1192 O.G. 68 (November 19, 1996) and MPEP 803.04). This not found persuasive. As stated in MPEP 8.03.04; "(n)ucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141."

2. Claim 77 has been amended

Claims 10-12 and 14-15 and 79, drawn to non-elected inventions, are withdrawn from examination.

Claims 16-78 are examined on the merits.

3. The rejection of claims 22-23, 26, 28-29, 34-35, 38, 40-41, 48-49, 52, 54-55, 62-63, 66, 68-69 and 72-75 under 35 U.S.C. 112, first paragraph, as containing new matter, based on the following recitations: "a heterologous polynucleotide" (claims 22, 34, 48, 62), "said heterologous polynucleotide encodes a heterologous polypeptide" (claims 23, 35, 49, 63), "operably associated with a heterologous regulatory sequence" (claims 26, 28,38,40,52,54,66,68), "except for one to thirty conservative amino acid substitutions" (claim 72), "wherein said substitutions is not more than 10" (claim 73), "wherein said substitutions is not more than 5" (claim 74), and "wherein said substitutions is not more than 3" (claim 75) is withdrawn.

The rejection of claims 17, 19 and 77 under 35 U.S.C. 112, first paragraph, as containing new matter, for the following recitations: "nucleotides 15 to 392 of SEQ ID NO:1" (claim 17), "nucleotides 12 to 392 of SEQ ID NO:1" (claim 19), "nucleotides 15 to 392 of SEQ ID NO:1" and "nucleotides 12-392 of SEQ ID NO:1" (claim 77) is maintained.

The applicant argues that support for these recitations can be found, *inter alia*, on page 11, lines 16-19 of the specification, which recites "(a) a nucleotide sequence encoding the BCSG1 polypeptide having the amino acid sequence in Figure 1 (SEQ ID NO:2); (b) a nucleotide

sequence encoding the polypeptide having the amino acid sequence of SEQ ID NO:2, but lacking the N-terminal methionine. As shown in sequence listing, nucleotides 12 to 392 of SEQ ID NO:1 encode a polypeptide having the amino acid sequence of SEQ ID NO:2; and nucleotides 15 to 392 of SEQ ID NO:1 encode a polypeptide having the amino acid sequence of SEQ ID NO:2, but lacking the N-terminal methionine. Applicant asserts that this disclosure is sufficient to convey to one of ordinary skill in the art that the inventors had possession of the invention of claims 17 and 19" (and 77) at the time the application was filed.

This is not found persuasive. The applicants broadly contemplated a genus of polynucleotides, those encoding the BCSG1 polypeptide having the amino acid sequence in Figure 1 (SEQ ID NO:2) and those encoding the polypeptide having the amino acid sequence of SEQ ID NO:2, but lacking the N-terminal methionine. No where in the specification is there support for the species of molecule which is nucleotide 15 to 392 of SEQ ID NO:1 or nucleotide 12 to 392 of SEQ ID NO:1, that is there is no evidence that, at the time of filing, the claimed nucleotides started specifically at residue 12 or residue 15 of SEQ ID NO:1. Thus, these recitations remain new matter.

4. The rejection of claims 31-42, 71-76 under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials, is withdrawn.

5. Claims 16-78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial, specific and credible asserted utility or a well established utility.

The specification discloses SEQ ID NO:1, the polynucleotide sequence of BCSG1, an mRNA, which when used as a hybridization probe can distinguish metastatic breast cancer tissue from normal breast tissue (p.48 of the specification). Thus, the polynucleotide sequence of SEQ ID NO:1 has utility as a probe for the detection of metastatic breast cancer. However, while it is noted that the polypeptide encoded by SEQ ID NO:1 has 54% sequence identity to the human Alzheimer's disease amyloid protein (see p. 46, lines 24-25), the function of this polypeptide

(amino acid sequence of SEQ ID NO:2, encoded by SEQ ID NO:1) is not known. Thus, polynucleotide sequences that encode the polypeptide of SEQ ID NO:2, or fragments thereof lack a specific, substantial and credible utility.

Claims 16-78 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial, specific and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. Claims 43-70 and 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 43-56 are drawn to polynucleotides **comprising** 50, 100 or 250 contiguous nucleotides of the coding region of SEQ ID NO:1. Claims 57-70 are drawn to polynucleotides **comprising** a nucleic acid which encodes an amino acid sequence selected from the group consisting of amino acids 94 to 107 of SEQ ID NO:2 and amino acids 120 to 127 of SEQ ID NO:2. Claims 78 is drawn to polynucleotides **comprising** nucleic acids of 50 or more nucleotides in length that hybridize to SEQ ID NO:1.

Thus, the claims are drawn to nucleic acid molecules that minimally contain only portions of SEQ ID NO:1 or encoding only portions of SEQ ID NO:2. Thus, the claims are drawn to a large genus of molecules, including any larger nucleic acid that contains within it the small portions of SEQ ID NO:1 identified. This includes not only the gene encoding the cDNA sequence of SEQ ID NO:1, but potentially other, as yet undiscovered, cDNAs which share homology in only this small region of sequence. In the case of small identified nucleic acid sequences claimed with open language, the genus of nucleic acid molecules comprising only a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of one species, the polynucleotide sequence of SEQ ID NO:1. The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed. Applicant are directed to the Revised Interim Guidelines for the

Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999, also available at www.uspto.gov.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER

June 2, 2000